

**Generic Name:** Darunavir-Cobicistat/  
Emtricitabine/Tenofovir Alafenamide

**Therapeutic Class or Brand Name:** Symtuza®

**Applicable Drugs (if Therapeutic Class):** N/A

**GPI Code:** 1210990420

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 9/20/2018

**Date Last Reviewed / Revised:** 5/28/2019

### PRIOR AUTHORIZATION CRITERIA

(may be considered medically necessary when criteria I through III are met)

- I. Adult patient with documented diagnosis of HIV- 1 infection.
- II. Patient fulfills ONE of the following criteria A or B:
  - A. Patient has no history of prior antiretroviral treatment.
  - B. Patient has been on a stable antiretroviral regimen for at least six months with virological suppression (HIV-1 RNA less than 50 copies/mL) AND has no known drug substitutions associated with resistance to darunavir or tenofovir.
- III. Patient has ONE of the following characteristics A or B:
  - A. Contraindication to integrase-strand transfer inhibitors (INSTI), such as dolutegravir, elvitegravir, and raltegravir.
  - B. History of poor adherence OR requires immediate antiretroviral therapy initiation prior to drug resistance testing (e.g., during acute HIV infection, pregnancy, or in the setting of certain opportunistic infections).

### EXCLUSION CRITERIA

- Coadministration of Symtuza® with the following drugs are contraindicated:

Drug Class	Drug(s) Within Class
Alpha 1-adrenoreceptor antagonist	Alfuzosin
Antianginal	Ranolazine
Antiarrhythmic	Dronedarone
Anticonvulsants	Carbamazepine, phenobarbital, phenytoin
Anti-gout	Colchicine (in patients with renal/hepatic impairment)
Antimycobacterial	Rifampin
Antipsychotics	Lurasidone, pimozide
Ergot derivatives	dihydroergotamine, ergotamine, methylergonovine
GI motility agent	Cisapride

Drug Class	Drug(s) Within Class
Herbal product	St. John's Wort
Hepatitis C direct acting antiviral	Elbasvir/grazoprevir
Lipid modifying agents	Lomitapide, lovastatin, simvastatin
PDE-5 inhibitor	Sildenafil (for treatment of pulmonary artery hypertension)
Sedatives/hypnotics	Midazolam (oral), triazolam

## OTHER CRITERIA

- Quantities of up to 30 tablets per 30 days.

## APPROVAL LENGTH

- Authorization:** 1 year.
- Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and the medication is effective. .

## APPENDIX

- N/A

## REFERENCES

- <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SYMTUZA-pi.pdf> .
- <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0> .
- Medi-Span®

## HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
5/28/2019	1. <b>Added</b> Lomitapide to lovastatin and simvastatin and <b>changed</b> drug class name from "HMG-CoA Reductase Inhibitors" to "Lipid modifying agents" <b>under Exclusion Criteria</b> .
9/20/2018	1. New policy.